1. **Purpose**

This document defines the policies and procedures for implementing and maintaining unique device identification. This contains the procedures and requirements for maintaining compliance to the UDI requirements.

1. **Scope**

This procedure applies to all medical devices that are manufactured, labeled, and/or distributed by the company.

1. **General** 
   1. **Definitions** 
      * **DI** – Device Identifier
      * **EUDAMED** – European Union Database on Medical Devices
      * **GMDN** – Global Medical Device Nomenclature
      * **PI** – Production Identifier
      * **UDI** – Unique Device Identification
   2. **Responsibilities**

**Regulatory Affairs** – Regulatory Affairs Management is responsible for ensuring continued compliance with the procedures specified in this document and by the regulatory authorities.

* 1. **Equipment and Materials** – N/A
  2. **Safety Precautions** – N/A
  3. **Training Requirement** –Regulatory personnel shall be trained to this document based upon their responsibilities.
  4. **Record Management** – UDI Records are managed and maintained by the Regulatory Department for a minimum of five (5) years following the last manufacturer of the associated medical device.
  5. **Reference Documents and Materials**

**FDA CFR 21 Part 830** – Unique Device Identification

**FDA Guidance** – Global Unique Device Identification Database (GUDID)

**MDR 2017/745** – EU Medical Device Regulation

**MDD 93/42/EEC** – EU Medical Device Directive

**ISO/IEC 15417 –** Information Technology – Automatic Identification and Data Capture Techniques – Code 128 Bar Code Symbology Specification

1. **Unique Device Identification (UDI) Procedure**
   1. **UDI Issuing Agency**

The company utilizes an accredited issuing agency to establish a unique company code for UDI. The company has registered with this agency and obtained an appropriate company code to identify all products produced and distributed.

* 1. **UDI Components**

The Unique Device Identification system utilized includes two components: the Device Identifier and the Production Identifier. When incorporated into barcode format, these may be separated into two barcodes or concatenated into a single barcode.

* + 1. **Device Identifier (DI)**

The Device Identifier identifies the specific device or device family that is produced by the company and contains the following components:

* Company Code
* Product Code or Reference Code
* Unit of Measure (Packaging Configuration identifier)
  + 1. **Production Identifier (PI)**

The Production Identifier identifies the specific production lot from which the product was manufactured. The PI contains all the following information that appears on the product label. Examples include, but are not limited to:

* Lot or Batch Number
* Serial Number
* Expiration Date
* Manufacturing Date

1. **Barcodes**

The company utilizes the following specifications to ensure proper readability of barcodes on distributed products:

* Code 128 Symbology
* Human Readability Version below Barcode
* Minimum Print Quality of C/06/660
* Minimum X-dimension of 0.010 inch (0.25mm) at print quality of C/06/660
* Minimum X-dimension of 0.0067 inches (0.17mm) at print quality of B/06/660 or better
* Barcode Height = 5mm or 15% of Total Width of Barcode
* Each barcode contains a Unit of Measure from 0 to 9 (0 – Individual Product, 1 – Smallest Container of Individual Products, etc.)

1. **Global Unique Device Identification Database (GUDID) and European Database on Medical Device (EUDAMED)**

The company has established and maintains a GUDID account with the FDA and EUDAMED account (when operational) with the EU for applicable products. The Regulatory Affairs has the following responsibilities associated with these accounts:

* Ensuring the information submitted to the accounts is accurate and up-to-date.
* Establishing a Regulatory Contact
* Assigning Labelers, Coordinators, and Data Entry Users as necessary.

The Device Identifier for each medical device that is distributed in the USA is listed in the GUDID. The DI for each medical device with a CE Mark is listed in the EUDAMED. Only the DI is listed; the Production Identifier is not listed in the GUDID. The Device Identifier shall contain the smallest Unit of Measure associated with the product. The DI is maintained throughout the product life cycle. Once a product life cycle is ended, the Discontinue Date is entered into the system.

The following information is entered in the GUDID and EUDAM as applicable. For additional information on how to enter information into the system see the FDA GUDID Guidance document.

* Primary Device Identifier – The Base Package DI
* Package Information
  + Package DI
  + Qty per Package
  + Contains DI Package
  + Package Type
  + Package Discontinue Date (upon completion of life cycle)
  + Package Status
* Device Listing Information
  + FDA Premarket Submission Number
  + FDA Device Listing Number
  + FDA Product Code
  + Global Medical Device Nomenclature (GMDN) – International device type code. See [www.gmdnagency.com](http://www.gmdnagency.com) for additional information.
* Other Product Specific Information
  + Information Listed on Label
  + Information on Rx Only or OTC
  + Information on Product Sterility

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0025 |  |  | Initial release of the procedure for establishing and maintaining unique device identification for all medical devices. |